Plan Overview

A Data Management Plan created using DMPonline

Title: Investigation of Sex-specific Differences in Peri-operative Mortality for Vascular Surgery

Creator: Anna Louise Pouncey

Principal Investigator: Colin Bicknell

Data Manager: Anna Louise Pouncey , Janet Powell

Project Administrator: Anna Louise Pouncey , Janet Powell

Contributor: Colin Bicknell , Anna Louise Pouncey , Janet Powell

Affiliation: Imperial College London

Template: Imperial College London Generic DMP

Project abstract:

Research question Why do women experience higher mortality and complication rates following elective abdominal aortic aneurysm (AAA) repair? We will examine whether (potentially correctable) sex-specific differences in patient selection, anatomical complexity, preparation for and response to AAA surgery contribute to the disparity in outcomes. Background Operative mortality is observed to be higher in women than men for AAA repair. Differences remain following adjustment for age and co-morbidities, and the reasons for this are unknown. Sex-specific differences have been reported in the epidemiology and rupture risk of AAA. However, as the incidence of AAA is 5 times higher in men, the majority of evidence-based investigations, classification and care pathways have been tailored to them. This “one-size-fits-all” approach may leave women neglected. We updated a meta-analysis of sex-specific 30-day mortality, with novel secondary analysis of risk factors and peri/post-operative complications, for elective AAA repair. This confirmed a significantly higher mortality risk for women: open repair (OAR, OR1.49 [95%CI1.38-.162]); endovascular repair (EVAR) (OR1.87 [95%CI1.57-2.23]), despite a lower incidence of major pre-operatively identified risk factors such as coronary artery disease (OR0.65 [95%CI0.48-0.87]) and diabetes (OR0.85 [95%CI0.75-0.97]). Peri-operatively, women were more likely to require transfusion (OR 2.18 [95%CI2.08-2.29]), experience arterial injury (OR3.02 [95%CI1.62-5.65]), suffer ischaemic complications (bowel (OR1.90 [95%CI1.42-2.53]), lower limb (OR2.11 [95%CI1.32-3.77]), suggesting potential differences in anatomical/operative complexity. Post-operatively, a higher rate of cardiac (OR1.20 [95%CI1.04-1.39], respiratory (OR1.58 [95%CI1.21-2.06]), and renal (OR1.45 [95%CI1.22-1.72]) complications, and longer hospital stay were observed, which might be due to differences in pre-operative optimisation or in response to surgical stress. In order to mitigate these sex-specific discrepancies, detailed investigation is required. Aims and objectives With the aim to identifying key correctible causes, to enable quality improvement and equitable provision of care, we will explore the hypotheses that increased mortality and complications in women undergoing elective AAA repair are due to sex-specific differences in: 1. Recognition & management of pre-operative morbidities 2. Anatomical complexity 3. Selection for surgery 4. Surgical stress response Methods We will conduct: (1) A retrospective cohort study using national vascular registry (NVR) data to investigate differences in pre- operative status. Collaboration with NIHR-Health

Informatics Collaborative will enable exploration of pre- operative preparation and identified significant risk factors in greater detail. (2) A retrospective evaluation of >1000 scans for sex-specific differences in AAA, visceral and access artery morphology, and resultant association with peri-operative complications, with potential for expansion through collaboration with the UK- COMPASS study. (3) A discrete choice experiment to explore the role of patient sex as a variable on surgeon’s selection for operative repair and type of repair. (4) A prospective multi-centre cohort study, co-managed with PPI, to examine sex-specific differences in the stress response before and after AAA surgery. Anticipated impact and dissemination Results will be disseminated, with the help of patients and charitable foundations, (through social media, publications and presentations,) to patients, clinicians, researchers and relevant societies, in order to stimulate awareness and further research. Identified key correctible causes will be translated into future prospective studies of novel sex-specific treatment pathways to improve outcomes for women undergoing AAA repair.

ID: 83041

Start date: 01-10-2021

End date: 01-10-2024

Last modified: 18-07-2022

Copyright information:

The above plan creator(s) have agreed that others may use as much of the text of this plan as they would like in their own plans, and customise it as necessary. You do not need to credit the creator(s) as the source of the language used, but using any of the plan's text does not imply that the creator(s) endorse, or have any relationship to, your project or proposal

Investigation of Sex-specific Differences in Peri-operative Mortality for Vascular Surgery

Administrative details

Project Name/Title

Investigation of Sex-Specific Discrepancies in Peri-operative Mortality and Morbidity following Elective Abdominal Aortic Aneurysm Repair

Principle Investigator/Researcher

PhD candidate: Miss Anna Louise Pouncey
PI: Mr Colin Bicknell

ORCID iD (if applicable)

ORCID ID: 0000-0003-2329-6193

Project Description

This project aims to investigate why women have a higher risk of death and complications from abdominal aortic aneurysm repair compared to men. The project will examine whether there are sex-specific differences in:
1. Recognition and management of pre-operative co-mobidities
2. Differences in anatomy
3. Differences in selection for surgery
4. The stress response to surgery

With the aim to identifying key correctible causes, to enable quality improvement and equitable provision of care.

Data Collection

What data will you create or collect?

Project 1 - Analysis of national registry data (+/i HES/ONS), handled by the Imperial BDAU.
Project 2- Analysis of anonymised CT scans - morphological assessment of anonymous DICOM data
Project 3 - Discrete choice experiment - collection of anonymous preference data from vascular surgeons
Project 4 - Prospective cohort study - collection of health data from patients undergoing AAA repair.
Raw data will be analysed and expressed as graphs, tables and annotated images, some of which, it is expected, will be published.

What file formats will be used?

File formats will be used in accordance with data type and in keeping with the latest Imperial College London policy for data handling, management and storage (i.e. .xls, .rmd, .pdf, .doc, .eps, .mp3)
All data files will be saved in a suitable format for cross-platform compatibility, exchangeability and long-term access (i.e. conversion of .xls files to .csv).

Will you be reusing existing data (e.g. data sourced from a 3rd party data provider)?

- Yes (please give details)

Project 1 - Analysis of national registry data (+/i HES/ONS), handled by the Imperial BDAU.

Will you create any software or write any code to process or analyse data?

- Yes (please give details)

Standard code in R will be used for analysis of data, and stored on GitHub Enterprise in order to provide extra security for sensitive data. Data is stored on-premise within College and you need a College user account to log in and create repositories.

Ethics and Legal Responsibilities

Does your research involve human participants?

- Yes

Have you applied for/obtained ethical approval?

- Not yet, but I will

Ethical approval has been obtained for the first 3 components of the project. Ethical approval for the 4th project, a prospective cohort study is currently in process.

Have you obtained informed consent?

- Not yet, but I will

Will you be processing/collecting personal data?

- Yes

Will you be processing/collecting special categories of personal data (please select all that apply)?

- Health data

Are there any IP or copyright restrictions which might influence your use or sharing of the data?

- No

Data Documentation and Metadata

How will you organise your files and folders and manage different versions of your files?

A consistent system of file naming and an organised folder structure will ensure easy retrieval. This will involve creating meaningful but brief names and using file names to classify types of Files. The DMP will be updated with the system of file naming utilised for the project.

What documentation and metadata will accompany your data?

All datasets will be thoroughly annotated with meta data to provide users with all necessary details on the origin or manipulation of the data in order to favour and facilitate re-use and reproducibility.

A data dictionary will be created that defines the table definition, table fields, and table field data types.

For prospectively collected data, data will be identified by the date it was gathered, the name of the investigator who obtained it, and a short descriptor. A detailed description of the data and experimental conditions will be included in an accompanying text file.

Will you be using any domain specific or widely used metadata standards to describe your data?

All metadata records will be in accordance with Vascular Society guidance and Imperial College reporting standards.

Data Storage and Security

How much data do you expect to generate?

- 1-10 TB

How will you store and back-up your data during the project?

Data will be backed up and stored in accordance with the latest Imperial College London policy.

How will you manage access and security?

Any personal or highly sensitive data stored on College servers will be encrypted and only accessed by authorised members of the project. Highly sensitive data will not be available from off-campus. I will consult with the ICT Security team for guidance on how to store personal data.
Data for project 1 will be managed by the Imperial BDAU.

Data Archiving and Sharing

What data should be kept beyond the end of your project?

Raw and analysed data from project 2-4 will be kept for a duration in accordance with Imperial College guidance standards. (https://www.imperial.ac.uk/research-and-innovation/support-for-staff/scholarly-communication/research-data-management/imperial-policy/)
Raw data from project 1 will be deleted at the end of the data sharing agreement in accordance with contract requirements.
Analysed data will be kept for a duration in a accordance with Imperial College guidance standards.

What are your plans for long-term storage and data sharing?

Data that can be shared unconditionally will made available when scientific manuscripts are published, such that they are readily accessible to other researchers, on a repository such as zenodo or figshare. Should restricted access be required this will be discussed and decided upon through consultation with the Imperial data management team. Relevant code will be also be made available via GitHub. (https://www.imperial.ac.uk/research-and-innovation/support-for-staff/scholarly-communication/research-data-management/archival-and-preservation/finding-a-research-data-repository--archive/)

Will there be any restrictions on accessing the data?

- Yes (please give details)

Data that cannot be shared publicly (e.g. to protect patient confidentiality) will be by request only. The PI and research team will review each request on case-by-case basis. Upon approval the data requester will be asked to sign a data sharing agreement. Contact email/s will be provided in relevant publications for data access enquiries by other researchers.

How will potential users find out about your data?

All published papers will include a data access statement providing details of where the dataset can be found and under what conditions it can be accessed.

Responsibilities and Resources

Who is responsible for implementing this plan?

Along with the PI (Colin Bicknell), members of the project team (Anna Pouncey, Janet Powell) will have responsibility for study-wide data management, metadata creation, data security and quality assurance of data.

Will you require any additional resources to deliver this plan?

No. We have costed in time and effort within the grant to prepare the data for sharing / preservation. We have sufficient storage and equipment to undertake these tasks.